| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D0047342 | 02/20/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wichita County Health Center | 211 E Earl Street, Leoti, KS | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>A review of manufacture's package insert for Bio- Rad Liquicheck Cardiac Markers Plus Control LT revealed the laboratory failed to follow manufacture's instructions for storage. . Findings were as follows a. Based upon Bio-Rad Cardiac Quality Control package insert states " Do not store this product in a Frost Free freezer'.At the time of the survey 1 package was stored in a standard refrigerator freezer (frost free freezer) This was confirmed in interview with Technical Consultant the CMS form 209 #1 on 02/20/2018 at 10:30 hrs. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by: |

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| | A review of Temperature and humidity logs and interview with staff revealed the laboratory failed to document the humidity for the laboratory as the Vitros the chemistry analyzer Sysmex XS 1000 hematology analyzer an requires specific humidity.. Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed to document the humidity 30% to 80% for the laboratory . b. At the time of the survey 02/20/2018 the laboratory failed to produce documentation of humidity ranges, This was confirmed by the Technical Consultant #1 from CMS 209 form on 02/19/2018 at 10:30 hours. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to follow a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with Technical Consultant #1 02/20/2018 at 14: 30 hrs. confirmed the laboratory failed to follow the policy, Quality Control level 3 for the analyte PSA was out of control for 4 days without corrective action . 02/09 /2017,0213/2017,02/14/2017 and 02/16/2017 |